

## Questions for the Advisory Committee

NDA 21-576

Methyl Aminolevulinate Cream 168/mg/g (MAL)

### **Question 1: Efficacy**

The investigator's manual included the following lesion preparation instructions for use, viz., *"tumor fragments from most lesions may be removed without damaging normal skin and without use of anesthetics"*.

Were lesion preparation instructions adequate to ensure sufficient consistency among operators?

### **Question 2: Efficacy**

Please discuss the adequacy of outcome measures as well as the number of patients and lesions to assess efficacy of MAL-PDT in the treatment of nodular BCC for:

- a) Six month post-treatment by histology only (not clinical) in two pivotal studies (no follow-up available)
- b) Two year clinical follow-up data in one open label randomized study and one open label non-randomized study

### **Question 3: Efficacy**

Has adequate evidence been presented to support a primary indication for the treatment of BCC for this product?

### **Question 4: Efficacy**

Given that the current standard of care (surgical excision) is generally accepted as providing a higher rate of cure than that reported in the studies for NDA 21-576, if approved, how might this information be conveyed in professional labeling?

### **Question 5: Safety**

Please discuss the adequacy of the safety assessment, including:

- a) the contact sensitization assessment
- b) adequacy of data on recurrence rates

### **Question 6: Overall Assessment**

Based on the safety and efficacy data, does the Committee find a favorable risk vs. benefit balance to support approval of this product?

### **Question 7: Additional Studies**

Please discuss whether any additional studies may be needed and whether these studies may be conducted after approval.

### **Question 8: Future Guidance in Product Development**

For future development of drug products for BCC, please discuss which measure(s) should be the primary efficacy parameters, e.g., clinical evaluation and/or histological clearing and time points as well as recurrence rates and appropriate time points.